K113361

APR - 3 2012

Section VII. 510(K) SUMMARY

Date Prepared
March 09, 2012

Name of Firm
Custom Spine, Incorporated
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
Phone: (973) 808-0019
Fax: (973) 808-0707

Official Correspondent
David Brumfield
Senior VP of Research and Development, Quality, and Regulatory
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
Phone: (973) 265-5043
Fax: (973) 808-0707
E-mail: dbrumfield@customspine.com

Establishment Number
3005129649

Device Name
Legally Marketed Trade Name: Proposed Name SECURIS Spinal Fixation System
Common Name: Pedicle Screw Spinal System
Device Classification: Class III
Regulation Number: 21 CFR 888.3070
Device Product Codes: NKB, MNI, MNH

Predicate Devices
Moss® Miami Spinal System (K933881, K955348, K964024, K983583, K022623), Optima® Spinal System (K031585), Synthes Pangea System (K103287), Custom Spine ISSYS LP (K070821, K 072866, K110099), ISSYS (043522).

Device Description
The subject Securis Spinal Fixation System consist of screws of various diameter and length, non-sterile, single use Cannulated Titanium (ASTM F136, Ti-6Al-4V)

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screws and set screws to be used in conjunction with 5.0 mm diameter Cobalt-Chrome-Molybdenum (CoCr, ASTM F1537) rods. The rods are provided in various lengths to form various configurations for the individual patients and surgical condition. Instruments and guide wires are made from various grades of stainless steel.

Indications for Use

"The Securis Spinal Fixation system is intended for immobilization and stabilization of the thoraco-lumbar-sacral spine (T1-S1) as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis)."

Materials

The screws and setscrews are made from titanium (ASTM F-136, Ti-6Al-4V) and the rods are made from Cobalt-Chromium- Molybdenum (Co-28Cr-6Mo, ASTM F-1537).

Performance Data

Bench testing was performed to support the equivalence of the proposed pedicle screw system in accordance with FDA Guidance "Guidance for Industry and FDA Staff: Spinal System 510(k) s." The following testing was performed in accordance with ASTM F1717: Static Compression Bending, Static Torsion, and Dynamic Compression Bending.

Substantial Equivalence Statement

Documentation is provided which demonstrates that the Securis Spinal System is substantially equivalent to its predicate devices in terms of its material, design, and indications for use, and performance characteristics. Those comparisons are made in the substantial equivalence tables and the executive summary comparing the materials used in the systems, indications for use, and mechanical test data. The design characteristics of the SECURIS Spinal Fixation System is similar in technology (interconnections between the polyaxial head and bone screw) as the previously cleared ISSYS LP ((K070821, K 072866, K110099) and ISSYS (K043522) Polyaxial Screw Systems.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Custom Spine, Incorporated
% Mr. David Brumfield
Senior VP of Research and Development, Quality and Regulatory
1140 Parsippany Boulevard, Suite 201
Parsippany, New Jersey 07054

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Re: K113361
Trade/Device Name: SECURIS Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: February 15, 2012
Received: February 15, 2012

Dear Mr. Brumfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section VI. INDICATIONS FOR USE STATEMENT

510(k) Number : K113361

The SECURIS Spinal Fixation System is intended for the immobilization and stabilization of the thoraco-lumbar-sacral spine (T1-S1) as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined by discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and previously failed fusion (pseudoarthrosis).

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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